

wherein the head and neck soft tissues include a native structure  
having an epithelial cell layer, connective tissue, and functional muscle.

### REMARKS

Claims 10 and 11 have been cancelled without prejudice.

Claims 1, 3, and 8-9 have been amended. Claim 1 has been amended to change "the a" to "a" to remove the antecedent basis issue. Claim 1 has also been amended to replace the word "a" with the word "the" in reference to removal of a portion of the vocal cord to provide antecedent basis for "the vocal cord." Claim 3 has been amended to delete the offending language to remove the antecedent basis issue. Support for this claim amendment is found throughout the specification, and in one particular instance at page 3, lines 28-30. Claim 8 has been amended to replace the phrase "single thickness sheet" with the phrase "single layer." Support for this claim amendment is found in the specification at page 9, line 26. Claim 9 has been amended to replace the phrase "the a damaged" with the phrase "a damaged" to remove the antecedent basis issue. Claim 9 has also been amended to replace the phrase "diseased or damaged tissue" with the phrase "head and neck soft tissues," and to incorporate the subject matter of claim 10 into claim 9. Support for this claim amendment is found in the specification at page 3, lines 20-22.

Claim 12 has been added. Support for this claim is found in the specification at page 12, lines 6-8.

Claim 1 stands rejected under 35 U.S.C. § 112, ¶ 2, for indefiniteness. Claim 1 has been amended to specify "a damaged or diseased portion of a vocal cord," thus, removing the antecedent basis issue. Withdrawal of the rejection of claim 1 under 35 U.S.C. § 112, ¶ 2, is respectfully requested.

Claim 3 stands rejected under 35 U.S.C. § 112, ¶ 2, for indefiniteness. Claim 3 has been amended to specify that the submucosa is tissue is "intestinal submucosa" with the

offending language having been removed. Withdrawal of the rejection of claim 3 under 35 U.S.C. § 112, ¶ 2, is respectfully requested.

Claim 8 stands rejected under 35 U.S.C. § 112, ¶ 2, for indefiniteness. Claim 8 has been amended to replace the phrase “a single thickness sheet” with the phrase “a single layer.” Withdrawal of the rejection of claim 8 under 35 U.S.C. § 112, ¶ 2, is respectfully requested.

Claim 9 stands rejected under 35 U.S.C. § 112, ¶ 2, for indefiniteness. Claim 9 has been amended to replace the phrase “the a damaged or diseased portion” with the phrase “a damaged or diseased portion” to remove any issue as to antecedent basis. Withdrawal of the rejection of claim 9 under 35 U.S.C. § 112, ¶ 2, is respectfully requested.

Claims 10 and 11 stand rejected under 35 U.S.C. § 112, ¶ 2, for indefiniteness. Claims 10 and 11 have been cancelled without prejudice obviating the Examiner’s rejection of these claims.

Claim 11 stands rejected under 35 U.S.C. § 101. Claim 11 has been cancelled without prejudice obviating the Examiner’s rejection of this claim.

The Examiner has rejected claim 1 under 35 U.S.C. § 102(b) as being anticipated by Wexler et al. The Examiner indicates that Wexler et al. discloses a method for repair of damaged vocal cord tissues comprising the steps of removing the damaged portion and replacing the removed portion with a graft construct comprising vertebrate submucosa. Applicants respectfully traverse the Examiner’s rejection of claim 1 under 35 U.S.C. § 102(b). Wexler et al. does not anticipate claim 1.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Wexler et al. describes a method for the repair of vocal cords by using a fat graft to repair injured vocal cords. The fat graft is implanted in a pocket cut in the vocal cord in a submucosal location (*i.e.*, the fat graft does

not comprise submucosal tissue, but rather is implanted in a submucosal location). As stated in Wexler et al. (page 669, paragraph four) with respect to implantation of the fat graft, “[i]nto this pocket a pad of fat (water volume displacement ranged from 0.2 to 0.4 mL) was placed.” (emphasis added).

Furthermore, the fat graft described in Wexler et al. is an augmentation graft rather than a graft that is used to repair a damaged or diseased portion of a vocal cord by replacement of the damaged tissue. The fat augmentation graft simply alters vocal cord structure to increase vocal cord compliance (*i.e.*, to enhance vibration), but does not participate in the repair of the damaged vocal cord tissue. As stated on page 669, first paragraph of Wexler et al., “[w]hereas submucosal injections of Teflon and other materials have been used routinely in phonosurgery solely to medialize the paralyzed vocal cord, for the present study a lighter and more compliant material was sought to enhance vibration of the damaged cover layer. A submucosal fat autograft was considered as one such possibility. Fat is a readily available, compliant, nonreactive biomaterial with relatively low metabolic requirements. Although the viscoelastic properties of fat have not been measured, it was expected to be more compliant than scar tissue or injectable Teflon, and thus more conducive to vocal cord vibration.”

Thus, Wexler et al. describes a fat graft for implantation in a submucosal location, and the fat graft functions as an augmentation graft rather than a graft that is used to repair a damaged vocal cord by replacement of the damaged tissue. Claim 1 of the captioned application is directed to a method for the repair and replacement of damaged vocal cord tissue, and claim 1 requires the use of submucosal tissue or basement membrane to replace and to repair the damaged vocal cord tissue. Accordingly, Wexler et al. cannot anticipate claim 1 because Wexler et al. teaches a fat graft for vocal cord augmentation rather than a submucosal tissue or basement membrane graft for replacement and repair of damaged vocal

cord tissue as required by claim 1 of the captioned application. Withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) is respectfully requested.

The Examiner has rejected claim 9 under 35 U.S.C. § 102(b) as being anticipated by Cobb et al. The Examiner indicates that Cobb et al. discloses a method for the repair of damaged head and neck soft tissues (*i.e.*, dura mater tissue) comprising the steps of removing the damaged or diseased tissue and replacing the removed tissue with a graft construct comprising vertebrate submucosa. Applicants respectfully traverse the Examiner's rejection of amended claim 9 under 35 U.S.C. § 102(b). Cobb et al. does not anticipate amended claim 9.

Cobb et al. describes a method for the repair of damaged dura mater tissue using a submucosal tissue graft. Claim 9 has been amended to specify a method for the repair of head and neck soft tissues using submucosal tissue or basement membrane grafts wherein the head and neck soft tissues are selected from the group consisting of vocal cord, larynx, palette, attached gingiva, nasal, and auricular tissues. Accordingly, Cobb et al. cannot anticipate claim 9 because claim 9 is directed to the repair of head and neck soft tissues selected from the group consisting of vocal cord, larynx, palette, attached gingiva, nasal, and auricular tissues, and Cobb et al. does not teach repair of these tissues. Withdrawal of the rejection of claim 9 under 35 U.S.C. § 102(b) is respectfully requested.

Claims 2-3 and 5-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wexler et al. in view of U.S. Patent No. 5,573,784 (the '784 patent). The Examiner contends that Wexler et al. discloses the claimed invention except for the derivation of the submucosal tissue, and that the '784 patent discloses the use of an intestinal submucosa tissue graft. According to the Examiner, it would have been obvious to a skilled artisan to provide Wexler et al. with a tissue graft made of intestinal submucosa tissue, as disclosed in the '784 patent in order to repair diseased or damaged tissues. Applicants respectfully traverse the Examiner's rejection of claims 2-3 and 5-7 under 35 U.S.C. § 103(a).

Wexler et al. in combination with the '784 patent does render obvious the invention of claims 2-3 and 5-7.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992.). Applicants contend that there is no motivation discernible from either the cited references themselves or the general knowledge available to a skilled artisan to combine Wexler et al. with the '784 patent. As discussed above, Wexler et al. describes a fat graft which functions as an augmentation graft rather than a graft that is used to repair a damaged vocal cord by replacement of the damaged tissue, *i.e.*, the fat graft is not placed at the site of vocal cord damage, but rather is placed in a pocket cut in a location underneath the damaged vocal cord surface. Moreover, the fat graft is an augmentation graft that simply increases vocal cord compliance, but does not participate in the repair of the damaged vocal cord tissue itself.

In contrast, the intestinal submucosa graft described in the '784 patent, like the grafts specified in Applicants' claimed method, is a graft that is placed at the site of tissue damage, and directly participates in the repair process by inducing replacement of the damaged tissue. Therefore, contrary to the Examiner's contention, it could not have been obvious to a skilled artisan to provide Wexler et al. with an intestinal submucosa tissue graft, as disclosed in the '784 patent, "in order to repair diseased or damaged tissues" in place of the fat graft described in Wexler et al. because the fat graft described in Wexler et al. does not participate in the repair process to induce replacement of damaged tissue. The graft described in Wexler et al. simply alters vocal cord structure to increase vocal cord compliance (*i.e.*, the fat graft alters vocal cord structure to make the vocal cord more conducive to vibration). Thus, the graft materials described in Wexler et al. and '784 patent

serve completely different functions and Applicants contend that there is no motivation for a skilled artisan to combine Wexler et al. with the '784 patent.

Moreover, even if there were motivation to combine Wexler et al. with '784 patent, the invention of claims 2-3 and 5-7 would not have been obvious over Wexler et al. in combination with the '784 patent at the time the invention was made. Neither the '784 patent nor the primary Wexler et al. reference suggests or even mentions a graft that participates directly in vocal cord repair. Accordingly, the lack of motivation to combine the cited references and the differences between the cited references and Applicants' claimed invention are such that the claimed invention could not have been obvious over Wexler et al. in view of the '784 patent at the time the invention was made. Withdrawal of the rejection of claims 2-3 and 5-7 under 35 U.S.C. § 103(a) is respectfully requested.

The Examiner has rejected claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Wexler et al. in view of PCT International Publication No. WO 98/25637. The Examiner contends that Wexler et al. discloses the claimed invention except for the use of vertebrate basement membrane, and that WO 98/25637 discloses the use of a basement membrane graft. Thus, this rejection is analogous to the § 103 rejection over Wexler et al. in view of the '784 patent. The arguments discussed above with respect to the § 103 rejection over Wexler et al. in view of the '784 patent apply with equal force to this rejection except as applied to a basement membrane graft. Withdrawal of the rejection of claim 4 under 35 U.S.C. § 103(a) is respectfully requested.

### **CONCLUSION**

The foregoing amendments and remarks are believed to fully respond to the Examiner's rejections. The claims are in condition for allowance. Applicants respectfully request allowance of the claims, and passage of the application to issuance.

Respectfully submitted,

A handwritten signature in cursive script that reads "Rebecca Ball". The signature is written in black ink and is positioned above the printed name and title.

Rebecca L. Ball  
Registration No. 46,535  
Attorney for Applicants

RVB:glt  
(317) 231-7511  
Indianapolis, Indiana 46204

Appendix to Amendment  
Marked-Up Version of Rewritten Claims Under 37 C.F.R. § 1.121(c)(1)(ii)  
Application No. 09/857,307

Please amend claims 1, 3, and 8-9 as follows:

1. (Amended) A method for the repair or replacement of vocal cord tissues comprising the steps of:

removing a damaged or diseased portion of a vocal cord, and  
replacing the removed portion of [a] the vocal cord with a graft construct comprising vertebrate submucosa or basement membrane.

3. (Amended) The method of claim 2 wherein the submucosa is intestinal submucosa [and comprises the tunica submucosa delaminated from the tunica muscularis and the luminal portion of the tunica mucosa].

8. (Amended) The method of claim 1 wherein the graft construct comprises a single [thickness sheet] layer of submucosa.

9. (Amended) A method for the repair or replacement of damaged or diseased head and neck soft tissues comprising the steps of:

removing [the] a [damage] damaged or diseased portion of the [diseased or damaged tissue] head and neck soft tissues, and

replacing the removed portion of tissue with a graft construct comprising vertebrate submucosa or basement membrane,

wherein the head and neck soft tissues are selected from the group consisting of vocal cord, larynx, palette, attached gingiva, nasal, and auricular tissues.